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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,968	10/18/2001	Sconyoung Kim	PD-0461	7257

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 07/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,968

Applicant(s)

KIM ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This office action is in response to Amendment B, paper no: 5, received 7/9/03, in which applicant withdrew claims 1-8, amended claims 9 and 11, and added new claims 13-16.

Applicant's election of group III, claims 9-12, with traverse of groups I and II (claims 1-7 and 8, respectively) in Paper No: 5 is acknowledged. Applicant put forth no reasons for the traversal, therefore the election will be treated as an election without traverse.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-16 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites a method for evaluating the physical stability of a protein formulation, this is indefinite for not pointing out if a specific protein is envisioned for evaluation or if all proteins can be evaluated using this method.

Claim 9 further recites "an agent that produces an observable signal", this is indefinite for failing to define the agent and the observable signal.

Claim 9 recites “ a controlled stress”, this is indefinite for failing to specify the controlled stress.

Claim 10 recites the controlled stress is agitation, this is indefinite for failing to specify an amount of agitation (time, rpm's).

Claim 11 recites the observable signal is a fluorescent signal, this is indefinite for failing to specify the type of fluorescent signal used and the amount of fluorescent signal required.

Claims 12-16 are included in this rejection for depending upon a rejected claim.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 9-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Nielsen, Biochemistry, 2001, vol. 40, pp-6036-6046 (published on the web on 4/24/01).

The instant invention is drawn to a method of evaluating the physical stability of a protein formulation, by preparing a statistically relevant number of samples, applying a agitation on the samples, monitoring the fluorescent signal produced by Thioflavin –T in the samples, applying a survival analysis to the data obtained for each sample, and comparing the survival analysis for each sample type.

Nielsen teaches the effect of environmental factors on the kinetics of insulin fibril formation, see title. Nielsen discloses that physical and chemical instability problems are among the most challenging tasks in development of protein delivery systems, see page 6036, first paragraph. Nielsen teaches the kinetics of insulin fibril formation by investigating the effects of

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agitation and Thioflavin-T (ThT), see page 6037, column 1, 5th paragraph and column 2, 1st paragraph. Nielsen discloses that 20uM ThT was used in sample analysis, see page 6037, column 2, 5th paragraph. Nielsen teaches the insulin was incubated with continuous shaking at 960 rpm at 37C with an excitation of 444nm and emission of 485 nm bottom reading, see page 6038, column 1, 3rd paragraph. Nielsen discloses that vigorous agitation attenuated the effects of insulin concentration or ionic strength indicates that agitation is a particularly critical factor, see page 6044, column 1, 2nd paragraph. Nielsen teaches that ThT did not effect the kinetics of insulin, see page 6042, column 1, 2nd paragraph. Nielsen discloses a sample size of 500ul, see page 6037, column 2, 5th paragraph. Nielsen teaches the influence of insulin concentration on insulin fibril formation monitored by ThT fluorescence at 37C with vigorous agitation at 960 rpm, see page 6039, column 2, Figure 2B.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen, Biochemistry, 2001, vol. 40, pp-6036-6046 (published on the web on 4/24/01).

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The reference is relied upon for reasons discussed *supra*.

Based upon the beneficial overall teachings provided by Nielsen with respect to such protein sample analyses, if not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust particular conventional working conditions therein (e.g., running a statistically relevant number of identical protein samples and/or using a commonly employed comparative analysis thereon)-i.e., the adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT

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7/28/03

RT


CHRISTOPHER R. TATE
PRIMARY EXAMINER